

**UkrAm Study of Thyroid Cancer and Other Thyroid Diseases in Ukraine
Following the Chernobyl Accident**

Progress Report for Quarter Beginning **1 December 2000** and Ending **28 February 2001**

Project Manager

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I. Executive Summary

For the reported period, the main efforts of the Project staff were directed towards completion of Project cohort formation and preparation for the second cycle of screening. In the current quarter information materials in order to maintain contact with cohort members who have gone through the first cycle of screening have been developed: seasonal greetings cards, information booklets, invitation to the second cycle of screening - examination by fixed and mobile teams, as well as an invitation letter to dosimetry interview for the mothers of those cohort members who were born in 1977 - 1986.

Primary invitations have been sent out to 451 cohort members from Selection 2 who have been screened in December 2000.

In December 2000 a total of 556 cohort members went through screening examination. Thus, as of January 1st, 2001 the Project cohort consisted of 13243 subjects.

Nodular goiter has been found in 18 patients (all these patients were referred to fine-needle aspiration biopsy [FNA] of thyroid nodular formations). 20 FNAs have been performed in patients with thyroid neoplasias revealed (18 have been found in the current quarter, and two in the previous one). According to FNA data, in 3 patients cytological changes corresponded to those of thyroid carcinoma, and in one patient a B-cell neoplasia has been revealed. All these patients have undergone surgery. The diagnosis of papillary thyroid carcinoma has been confirmed by a postoperative histological study. Three subjects with the diagnosis of nodular goiter have been operated on.

According to the results of examination, final endocrinological conclusions have been delivered to 2146 patients (among them 316 with revealed thyroid disorders). 1267 final conclusions have been transmitted to the local medical staff of controlled raions.

Within the reported period, the Central Laboratory has performed TSH tests in 1512 subjects, antiTPO in 1512 persons, ABTG in 1512 subjects, thyroglobulin in 1512 persons.

For the reported period, the Data Coordinating Center has prepared and transmitted 3500 complete sets of medical screening Forms of cohort members to the Data Processing Center of the University of Illinois.

Seasonal greetings cards and information booklets have been sent out to all the 13243 cohort members.

On February 6-7, 2001 a training for the Ukraine-U.S. Project staff has been performed in view of the second cycle of screening.

II. Report on Tasks

4. Enroll and maintain participation of subjects in the study

4.1 Develop informational materials for study subjects (letters, brochures, cards, newsletters)

In the current quarter were developed informational materials for maintaining contacts with cohort members who came through the first screening circle and materials which will be used for invitation for the repeated screening circles. For maintaining contacts with cohort members were developed New Year cards and information letters. Were prepared also letters of invitation for the 2-nd screening circle for examination by fixed and mobile teams and invitation letter for dosimetry interview for mothers of cohort members born 1977 - 1986

Operational difficulties encountered in accomplishing the task. No

4.2 Send out initial invitation with information brochure

In the current quarter have been sent initial 451 invitations for cohort members with information brochure.

Invitations has been sent to other then study raions of Kyiv and Zhitomyr oblst:
Zhytomyr oblast – 375 invitations;
Kyiv oblast 66 invitations;

Operational difficulties encountered in accomplishing the task. No.

4.4 Maintain contact with subjects every 6 months

4.4.1 Send out New Year's cards

In the current quarter New Year's greetings were sent to all cohort members underwent first screening circle procedures – 13529 cards

Raion	<i>Number of greetings sent</i>
Kyiv oblast	2862
Ivankiv	812
Poliskiy	79
Kyiv city	869
Other raions of Kyiv oblast	1102
Zhytomyr oblast	3593
Narodichi	880
Ovruch	2260
Other raions of Zhitomyr oblast	453
Cherhihiv oblast	6789
Ripki raion	1507
Chernihiv raion	1910
Chernihiv city	1496
Kozelets raion	1835
Other raions of Chernihiv oblast	41
Other oblast of Ukraine	15
Total number of New Year's greetings	13259

4.4.2 Send out newsletters to subjects

All cohort members screened for the first time (13259) were send an information letters (see 4.4.1)

Out of total number of letters sent 45 returned due to the wrong address – 45 cohort members sent their addresses since the time of examination.

5. Conduct initial screening examination of subjects

5.4 Sent invitation letters to schedule appointments for examination

In current quarter proposed appointment dates for examinations were sent with all mailed correspondence. Invitation letters with appointment dates were sent to cohort members living in Kyiv,

other than study raions of Zhytomir and Kyiv oblast – 451. In Narodichy raion of Zhytomyr oblast, Ivankiv raion of Kyiv oblast and other than study raions of Kyiv oblast (Polisskiy and Makariv raions), examination date has been determined by medical staff based on the results of personal contacts with cohort members. For the examination by fixed team came 430 cohort members.

For the examination by mobile team came 126 cohort members.

Were sent 100 repeated invitations with suggested appointments dates to persons who haven't attended their appointments for FNAB and 50 invitations for repeated determination of the levels of thyroid hormones in blood.

Operational difficulties encountered in accomplishing the task. No.

5.5 Perform screening examinations

Results of the work. The results of primary screening of cohort members for the period from December 1, 2000 to February 28, 2001 are presented in the report (Table 6). 556 cohort members have been examined. In 71 persons examined a diffuse goiter, in 18 patients a nodular goiter have been revealed (all of them have been referred for FNAB of thyroid nodules).

Operational difficulties in the process of work: no difficulties.

5.5.1 Conduct screening examinations (dosimetry interview)

Results of the work. The results of the work performed cover the period from 1/12/2000 until 28/02/2001 (Table 1 and Table 2).

Over the reported period, primary screening of cohort members has been completed; examinations as well as dosimetry interviews have been performed only in December 2000. 561 persons have been interviewed in December. A total of 13151 cohort members have gone through dosimetry interview during the period of primary screening.

In the current quarter 2 cohort members did not have dosimetry interview (out of the subjects having been examined at the Fixed Center in Kyiv from Selection 2). A total of 104 examined cohort members have not gone through dosimetry interview. As compared to the previous quarter, the number of cohort members without dosimetry interview has decreased by 1 person, having gone through interview following repeat invitation.

There are cohort members (27 persons) who have been invited to screening, have gone through dosimetry interview, but have not been included into the computer file of examined subjects established by the DCC. As compared to the previous quarter, the number of such cohort members has decreased by 12 persons because the DCC has key-entered information on these cohort members into the file of

examined subjects. Perhaps, after consideration 27 cohort members who have not been included there so far will be added to the file as well. Decisions about these cohort members will be taken after common discussion by the DCC and Epidemiology Group.

Difficulties encountered in the process of work. No difficulties.

5.6 Notify subjects of final screening results

For the reported period, local medical staff of study raions received for further distribution the following number of final medical conclusions:

	Raion	Number of final medical conclusions
1	Ivankiv raion	80
2	Kozelets raon	152
3	Ripky raion	141
4	Chernihiv raion	34
5	Town of Chernihiv	262
6	City of Kyiv	398
	Total	1067

Operational difficulties encountered in accomplishing the task. No.

Table 1. Distribution of cohort members having gone through dosimetry interview in the first screening cycle, according to the place of screening

	Selection I (Number of records = 20,071)			Selection II (Number of records = 14,021)			Total (Number of records = 34,092)		
	Total number		Changes after previous quarter	Total number		Changes after previous quarter	Total number		Changes after previous quarter
	#	%	#	#	%	#	#	%	#
Total of subjects having gone through dosimetry interview	8337	100.0	231	4131	100.0	330	3779	100.0	561
1. In Fixed Center in Kyiv	2345	28.1	209	1434	129.8	1228	3779	128.7	437
2. In Mobile Team	5992	71.9	22	3380	70.2	102	9372	71.3	124

Table 2. Status of screening activity for those cohort members who have been examined in the first screening cycle

	Selection I (Number of records = 20,071)			Selection II (Number of records = 14,021)			Total (Number of records = 34,092)		
	Total number		Changes after previous quarter	Total number		Changes after previous quarter	Total number		Changes after previous quarter
	#	%	#	#	%	#	#	%	#
Total of subjects having undergone screening examinations	8433	100.0	228	4822	100.0	332	13255	100.0	560
Subjects having not gone through dosimetry interview	96	1.1	-3 ¹⁾	8	0.2	2	104	0.8	-1 ²⁾
Subjects who are missing in DCC and have undergone screening and dosimetry interview	15	0.2	-7 ²⁾	12	0.2	-5 ²⁾	27	0.2	-12 ²⁾

Footnote ¹⁾ – subjects who had been missed in the previous quarter have gone through dosimetry interview in the current quarter;

²⁾ – subjects who had not been included in DCC register have been key-entered into to the register in the current quarter

6. Conduct second screening of subjects

6.1 Review screening process and data collection forms, and revise as necessary

A detailed plan of organizing invitations and dosimetry interviews with 100 mothers of those subjects who were aged 10 years and less at the moment of the accident (pilot project for conducting dosimetry interviews with mothers according to new Forms). The plan provides for 8-10 mothers invited per day, conducting dosimetry interview with all mothers who have come on invitation, and with those subjects whose mothers have not come on invitation. During the time left, the interviewer conducts dosimetry interview with subjects born in 1968-1976 who have come to second screening (the number depends on time left).

New invitation Forms for the mothers have been developed.

Difficulties encountered in the process of work. The question remains unsettled whether dosimetry interview should be conducted according to new Forms after completing pilot project of interviewing 100 mothers.

According to the plan, self-questionnaires are being sent out only to the mothers. Those subjects who have come without their mother (out of those provided for by the plan), and those who were born before 1977 and are going through dosimetry interview (if the interviewer has enough time) answer without preliminary acquaintance with self-questionnaire questions. Thus, the respondents are under unequal conditions in the process of interviewing.

6.2 Conduct training sessions for interviewers

In February 2001 (February 7 to 9) the American epidemiologists have conducted a 3-day training session for Project staff attended by all the members of the Dosimetry Group, including the interviewers. The session was an example for conducting additional special training for interviewers according to new Dosimetry Questionnaire Forms. In February the members of the Dosimetry Group have held 8 sessions with interviewers during which specially developed complex scenarios of subjects' behavior have been used. The training sessions have revealed some shortcomings of new Questionnaire Form, what does not enable to reflect multiple (>3) changes in milk consumption due to subject's relocations. Special rules of filling in questionnaires have been developed for such cases.

Difficulties encountered in the process of work. No difficulties.

6.3 Send invitation letters to schedule appoints for examination

In the reported period were send invitations for the repeated screening examination which will start on the 1 2th of March 2001.

Ivankiv raion of Kyiv oblast- 185 invitaitons

Kyiv city - 125 invitations

Ovruch raion of Zhytomyr oblast – 400 invitations

Invitations for dosimety interviews were sent to mothers of cohort members born 1977-1986.

Ivankiv raion – 50 invitations

Kyiv city – 50 invitations

Operational difficulties encountered in accomplishing the task. No.

7. Determine which subjects have developed thyroid cancer or other thyroid diseases

7.2 Conduct FNA on appropriate subjects and refer appropriate subjects for surgery

Results of the work. FNA has been conducted on 20 patients with revealed thyroid neoplasms (18 ones have been found in the current quarter and 2 in the previous quarter). 2 patients from the previous quarter have been reexamined due to noninformative cytology conclusions (1 nodular goiter, 1 noninformative conclusion). According to FNA data in 3 subjects cytological changes corresponded to those of thyroid carcinoma, and in one (female) patient a B-cell neoplasia has been revealed. All patients underwent surgical treatment. Following postoperative histological study the diagnosis of papillary thyroid carcinoma has been established. 3 persons with diagnosis of nodular goiter - who had undergone FNA in the previous quarter and in which cytology showed signs of changes arousing suspicion of thyroid carcno~~ma~~ - underwent surgical treatment (these patients did not present themselves at the operation in the previous quarter).

Operation difficulties encountered in the process of work: no difficulties.

7.3 Provide final pathomorphologic diagnosis after surgery

For the reported period, following screening examinations, 7 cohort members (1 male, 6 females) have been operated on, among which four subjects belonged to selection 1, and three to selection 2 (Table 9). In 1986 three of these patients were residing in Kyiv oblast (Polisya raion, town of Prypyat), two in Zhytomyr oblast (Narodychi raion), and two in Chernihiv oblast (Chernihiv raion). As to their age,

there were 2 adolescents: a girl aged 16 and a young man aged 17, as well as 5 young adults (female) aged 19-29.

Following pathomorphological study of biopsy material, the diagnosis of papillary thyroid carcinoma has been established in all above cases.

A papillary microcarcinoma of minimum size (less than 1 mm) has been established in a girl aged 16 (ID , exposure dose 9.8 Gy, group "C") only following postoperative study of paraffin blocks in the presence of a multinodular adenomatous oxyphilic-cell goiter for which this patient had been operated on.

The size of 6 other papillary carcinomas was 9, 12, 15, 17, 22, and 30 mm. It should be noted that a tumor of 9 mm diameter removed in a young man aged 17 (ID , exposure dose 1.6 Gy, group "C"), which might also be qualified as a microcarcinoma, was characterized by signs of extrathyroid spreading and presence of bilateral metastases (T4N2Mx). As a whole, 4 out of 7 cases (57%) have been referred to T4 category, metastases of carcinoma to cervical lymph nodes have been determined in 4 out of 7 cases (57%) as well.

In one case a papillary carcinoma was determined in the presence of an obvious chronic thyroiditis (a female aged 23, ID exposure dose 3.1 Gy, group "C"). As a whole, as to thyroid exposure dose two cases belonged to the group "A" (0.08 and 0.09 Gy), one to the group "B" (0.4 Gy), and four to the group "C" (1.6 Gy, 3.1 Gy, 4.3 Gy, 9.8 Gy).

Histological processing of biopsy material has been performed. Additional histological specimens have been prepared from paraffin blocks of removed tumors, extratumoral tissue, metastasis of papillary carcinoma to regional lymph nodes for the morphologic data bank of the Ukraine-US Project, and for additional verification by the International Panel of experts-pathologists. Appropriate Pathology Forms have been filled in (Russian and English versions).

Besides, for the reported period material has been analyzed from patients with thyroid pathology (2 cases) who went through screening examination, but have been operated before the beginning of screening (Table 6). One case (Selection 1) represented a papillary thyroid carcinoma, and one case a follicular adenoma (Selection 2).

A thyroid carcinoma has been removed in 1992 in a girl born in 1981 having been evacuated from Prypyat (ID exposure dose 4.1 Gy, group "C"). The tumor belonged to diffuse-sclerosing variant of papillary carcinoma with typical signs of spreading of tumoral loci within the gland and lymphatic vessels in the presence of obvious thyroiditis, fibrous changes, large number of psammoma bodies.

A follicular adenoma with dominant microfollicular structure has also been removed in 1992 in a female born in 1972 having been evacuated from Prypyat (ID exposure dose 0.5 Gy, group

“B”).

Both patients had been operated at the Institute of Endocrinology. Histological specimens have been prepared from archival paraffin blocks and analysed; material has been selected for the morphologic data bank of the Ukraine-US Project; appropriate Pathology Forms have been filled in (Russian and English versions).

It should be stressed that 2 more cohort members went through screening examination as far back as previous quarter, who had been previously operated for thyroid pathology (one case of thyroid carcinoma, one case of benign pathology). So far, no histological material is available from these patients, no additional morphologic verification has been performed; that is why these cases have not been included in Table 6.

7.5 Complete laboratory tests for subjects examined

I. The following blood tests have been performed:

I. TSH: 1512 persons,

among which:

normal level (0.4-4.0 mU/l): 1418 (93.78%);

below the normal level: 19 (1.26%);

above the normal level: 75 (4.96%)

among which:

above the normal level (4.1-5.0 mU/l): 44 (2.91%);

above the normal level (5.1-10.0 mU/l): 27 (1.79%);

over 10.0 mU/l: 4 (0.26%).

2. Anti TPO: 1512 persons,

among which:

normal level (0-60 U/ml): 1389 (91.87%);

above the normal level: 123 (8.13%),

among which:

above the normal level (61-100 U/ml): 14 (0.93%);

above the normal level (101-500 U/ml): 51 (3.37%);

above the normal level (501-1000 U/ml): 15 (0.99%);

over 1000 U/ml: 43 (2.84%).

3. ABTG: 1512 persons,

among which:

normal level (0-60 U/l): 1448 (95.77%);

above the normal level: 64 (4.23%)

among which:

above the normal level (61-100 U/l): 16 (1.06%);

above the normal level (101-500 U/l): 40 (2.64%);

above the normal level (501-1000 U/l): 1 (0.07%);

over 1000 U/l: 7 (0.46%).

4. Thyroglobulin: 1512 persons,

among which:

normal level (2,0-70 ng/ml): 1402 (92.72%);

below the normal level: 43 (2.84%);

noninformative: 27 (1.79%);

above the normal level (71-200 ng/ml): 40 (2.65%)

among which:

above the normal level (71-100 ng/ml): 24 (1.59%);

above the normal level (101-200 ng/ml): 14 (0.92%);

above the normal level (201-300 ng/ml): 1 (0.07%);

over 300 ng/ml: 1 (0.07%).

5. Ca²⁺ level was not determined due to repair of calcium analyser.

For the reported period, urinary iodine excretion tests have been performed in 400 subjects who were children and adolescents at the time of the Chornobyl accident, are living in Polisia, Ivankiv raions, and City of Kyiv of Kyiv oblast, in Narodychi and Ovruch raions of Zhytomyr oblast, in Chernihiv raion of Chernihiv oblast, and underwent screening examination in the framework of the Ukraine-U.S. Project. Urinary iodine excretion was assessed by cerium-arsenite method according to A.D. Dunn's modification of R. Gutekunst's technique.

The results obtained show differences in iodine deficiency degree from one studied raion to another. So, in Polisia raion of Kyiv oblast the median of urinary iodine excretion was equal to 47 µg/l; in Ivankiv raion of Kyiv oblast: 52 µg/l; in the City of Kyiv: 77 µg/l. In Chernihiv raion of Chernihiv oblast: 29.5 µg/l. For Zhytomyr oblast: 36.5 µg/l in Narodychi raion, and 39.7 µg/l in Ovruch raion.

Thus, the results obtained point out a moderate degree of iodine deficiency in Chernihiv raion of Chernihiv oblast, in Ovruch and Narodychi raions of Zhytomyr oblast, and Polisia raion of Kyiv oblast; a mild degree in Ivankiv raion of Kyiv oblast and City of Kyiv of Kyiv oblast.

7.6 Complete final endocrine summary for each subject

According to the results of examination, a final endocrine summary has been prepared for 2146 subjects (among them 316 patients with revealed thyroid pathology).

Operational difficulties in the process of work: no difficulties.

7.9 Conduct expert reviews of thyroid pathology for subjects who had surgery

Histological preparations from all above cases will be presented to the International Panel of experts-pathologists (Milan, Italy, April 20-22) for additional verification.

8. Develop data management system, and key enter data collected for the study

8.1 To develop a computer database for data storage

A system has been developed for visualizing USI data collected during the first screening. The program has been integrated to the main program complex. 27 850 graphic images for IO 441 cohort members have been added to the database. Images for cohort members having USI data only on thermal paper, have been scanned. The scanned images have been added to the general DB of images.

A data convertor for transferring data processed by UIC Center has been developed.

Computer equipment has been received for ensuring mobile and fixed teams' operation. System software has been installed on the computers. The program of printing bar-codes for the second screening cycle at registration stations has been modified. Besides, notebooks and desktops have been equipped with a program and database developed by the DCC. The registrars and USI staff have been taught to handle these programs.

A program for printing information about relatives from Locator Form has been developed, as well as a program for printing summary data on screening results.

All necessary materials for sending out seasonal greetings cards to all cohort members have been prepared.

97 invitations for aspiration biopsy have been sent out by the DCC along with clinical group.

Invitations for repeat hormonal tests have also been sent out. Lists have been prepared to be transmitted to local medical staff in raions where are living those cohort members who had not come to FNA. Lists of cohort members who went through primary screening in 1998-1999 have been prepared in order to invite them for the second screening cycle.

8.3 Key-enter information for collecting data into the database

Input of Fine Needle Aspiration and Cytology Forms was continued. 49 and 43 Forms have been entered, respectively. Data from registration logs on patients referred to aspiration biopsy have been key-entered.

For the reported period, 3500 sets of screening Forms have been prepared and transmitted to the Data Processing Center of the University of Illinois (Institute of Pediatrics, Obstetrics, and Gynecology). In addition, over the reported period, more than 3000 protocols of examinations with results of hormonal tests have been prepared and given to endocrinologists for final endocrinological conclusion. All sets of Forms with final diagnoses have also been transmitted to the Data Processing Center (Institute of Pediatrics, Obstetrics, and Gynecology).

8.4 To perform routine editing in certain parts of the database

Processing and input of the following data have been performed over the reported period:

- Preparing labels bearing addresses and lists for inviting cohort subjects' to screening (see 4.2). All information concerning invitations by mail and results of contacts with cohort members by phone has been key-entered into the database of contacts.
- Correcting the file of the database of contacts. Input of data on the results of contacts with cohort members, lists, dynamics of invitation by local medical staff has been performed. A total of 2204 contacts with cohort members (1503 by medical staff, 65 by phone, and 636 invitations by mail) have been key-entered and added to the database of contacts.
- Input of data from fixed and mobile teams' registration logs on cohort members who have been screened.

Correction of passport section of the database on those cohort subjects who have undergone screening, based on information from screening Forms. Passport data (date of birth, mail address) have been checked and supplemented with 761 addresses of cohort members. Input of data from accompanying logs of blood and urine collection has also been performed. Distribution according to the completeness of going through all screening stations by cohort members is presented in Table 5.

9. Calculate estimate of dose and uncertainty for each study subject

9.1 Determine the appropriate methods for calculating I-131 dose

9.1.1 Develop and field test dosimetry questionnaire

Results of the work. Prepared Russian versions of three Forms of Dosimetry Questionnaire and two Forms of Instructions for interviewers, common for the Ukraine and Belarus, have been agreed at the Trinational working Meeting in Kyiv in December 2000, and are used to field test the Questionnaires.

In the process of primary screening in December 2000, field testing of Questionnaires has been performed to find out how much time an interview took, and what was the rating of answers and attendance of interviews by the mothers. Based on new Forms 19 persons have been questioned (9 mothers, 3 mothers who were nursing at the moment of the accident, 7 subjects born before 1977). On average, an interview based on new Questionnaires takes 28 min, interviewing nursing mothers - 13 min. Out of 22 mothers invited to interview 9 have presented themselves (41%).

According to the results of field test and training sessions for interviewers on February 7 to 9 in Kyiv, some insignificant editorial corrections have been introduced into Questionnaires and Instructions. The agreed versions of Questionnaires have been transmitted to the printing-house in order to have the necessary number of Questionnaires printed for the pilot Project to interview 100 mothers.

Difficulties encountered in the process of work. No difficulties.

9.1.2 Derive the thyroid dose rates from the direct thyroid measurements

Results of the work. Verification has been performed of a dosimetry model and model to estimate incorporated radiocesium according to the data of spectrophotometric thyroid measurements made in the late period of the accident (after June 10, 1986) by GTRM type spectrometers. Relationship between sensitivity of GTRM type devices and ^{131}I and $^{134,137}\text{Cs}$ isotopes, obtained in model experiments at the previous stage, have been used in the process of verification.

Difficulties encountered in the process of work. No difficulties.

9.1.8 If feasible, develop an independent dosimetry method based on environmental transfer processes

Results of the work. In the framework of the Project reconstruction has been started of the dynamics of radioactive contamination of the air and underlying surface with iodine, tellurium and cesium radioisotopes in the initial period of the accident, based on mathematical modelling of spreading of radioactive fallout in the atmosphere above the Ukraine territory. With this purpose, a regional model of

atmospheric transfer - LEDI - developed at the Scientific Center for Radiation Medicine is being used. In the current quarter, collection, processing, and review of meteorological data being used as input information for the model, have been performed: a) data of atmospheric radiosounding that had been performed by the network of aerological stations of the State Committee for Hydrology and Meteorology of the Ukraine, namely, vertical profiles of temperature, velocity and direction of the wind, pressure in 9 places of sounding located in the Ukraine territory; b) data of measurements by the network of the State Committee for Hydrology and Meteorology that include the values of 12-hour sums of fallout in 103 meteorological stations and 411 meteorological posts of Ukraine (in order to take into account the contribution of damp deposition of iodine in the ground) for the period from April 25 to May 7, 1986.

An analysis has been made of using data of measurements of the amount of fallout for individual meteorological stations for parameterization of moist deposition in the model. A preliminary analysis of the influence of space averaging of the data of measurements of sums of atmospheric fallout on the results of calculations of moist deposition.

Difficulties encountered in the process of work. Taking into account the possibility of using this model in calculations of spreading of radioactive fallout above the territory of Belarus, it would be desirable to obtain analogous data of meteorological measurements that have been made in Belarus.

9.1.9 Analyse the answers given by respondents (completeness, reliability, statistical distributions, etc.)

A statistical analysis of all dosimetry questionnaires collected in the process of primary screening (13,151 questionnaires) has been made. The parameters of distribution of milk, greens consumption levels depending on subject's year of birth, gender, type of locality of residence at the time of the accident, have been estimated. An analysis of territorial and provisional specificity of the levels of consumption of main dose-forming foodstuffs has been made as well. The estimated parameters of distribution might be used as average age-related levels of consumption in the absence of individual questionnaire information.

The following analyses have been performed on the complete file of collected questionnaires: (1) analysis of the number of mothers who have come to dosimetry interview (or those who have answered the questionnaire sent by mail) depending on subject's age at the moment of the accident; (2) analysis of the reliability of respondents' memory depending on the type of respondent, subject's age at the moment of the accident.

9.1.10 Document: (1) the history of direct thyroid measurements

Results of the work. To meet with Dr. Kovtun and other collaborators who had been involved in thyroid activity measurements in Ukraine in 1986, a travel to St Petersburg has been organized in May (15 to 21.05, 2000). During the meetings, a number of issues have been stated: organization and performance of direct thyroid measurements, size of collimators for SRP 68-01 devices recommended in Ukraine, sources that had been used for device calibration, persons responsible for performance of measurements in Chernihiv oblast.

Besides, a meeting with Dr. Moroz and Dr. Yushkevych has been organized in St Petersburg, dealing with issues connected with analysis of the results of direct measurements of the activity of different radionuclides in objects of the environment in Ukraine in May-June 1986.

Difficulties encountered in the process of work. No difficulties.

III. Work Planned for the Next Two Quarters

The main task for Project implementation for the period March-May 2001 is performance of the second cycle of screening of cohort members.

1. Start the second cycle of screening of cohort members on March 12th, 2001.
2. Invite to the screening all cohort members who went through examination in 1998 and 1999.
3. Use three possible variants of screening performance:
 - by mobile teams;
 - subjects come by themselves to the Institute's Clinic for examination by the fixed team;
 - subjects are brought over by the Project bus to the Institute's Clinic for examination by fixed team.
4. Collect information on changes in the addresses of those cohort members who went through screening in the framework of the Project, and inform in time the Data Coordinating Center on cohort members' new address.
5. Maintain regular contacts with cohort members.
6. Inform in time the cohort members on the place and time of performance of a regular examination.
7. Ensure attendance to the examination of all cohort members according to the lists transmitted by the Institute of Endocrinology.
8. Follow closely the schedule of mobile teams' operation.
9. Create favourable conditions during patients' examination by Institute's mobile teams.
- IO. Prepare the second joint Meeting of the Binational Advisory Group of the Ukraine-U.S. Thyroid Project (Kyiv, Ukraine, May 10th-11th, 2001).

Table 1. Tracing of the Cohort

	Selection I (Records Selected = 20,071)			Selection II (Records Selected = 14,021)			Total (# of Records = 34,092)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Duplicate Record Found	1540		27	167		21	1707		48
Total Subjects	18531	100,0	-27	13854	100,0	-21	32385	100,0	-48
1. Address Found	12513	67,5	-169	8694	62,8	-90	21207	65,5	-259
1.1 Address in the Study Oblasts	11283	60,9	-180	8329	60,1	-92	19612	60,6	-272
1.1.1 Subject is Temporarily Absent	332	1,8	25	197	1,4	7	529	1,6	32
1.2 Address Outside Study Oblasts, Same Country	1230	6,6	11	365	2,6	2	1595	4,9	13
2. Emigrated to Another Country	445	2,4	3	189	1,4	0	634	2,0	3
3. Not Found	5425	29,3	130	4882	35,2	69	10307	31,8	199
4. Ineligible	16	0,1	3	1	0,0	0	17	0,1	3
5. Deceased	132	0,7	6	88	0,6	0	220	0,7	6

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 20,000 subjects who were originally selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the April 2000

Address Found - a current address has been found using at least one of the tracing sources

Temporarily Absent - subject is in the military, prison, school, hospital, or on vacation and is temporarily away from his/her permanent address

Address Outside Study Oblasts, Same Country - Includes those whose oblast of residence is known, but full address unknown and those for whom full address is known but it is outside the study oblasts

Not Found - a current address or vital status was unknown by all of the tracing sources (includes subjects known to be living in study oblasts, but full address is unknown)

Ineligible - subjects age at time of accident was determined to be out of the range

Table 2. Results of Contacts with Subjects for Screening Cycle 1 (Baseline Screening Examination Only**)

	Selection I (Records Selected = 20,071)			Selection II (Records Selected = 14,021)			Total (# of Records = 34,092)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Address Found in Study Oblasts	11283		-180	8329		-92	19612		-272
Invitation Sent/Subject Contacted	19019		421	8129		426	27148		847
1. First Invitation	13225	100,0	193	7086	100,0	258	20311	100,0	451
1.1 Accepted	5087	38,5	33	5040	71,1	108	10127	49,9	141
1.2 Refused	241	1,8	1	82	1,2	0	323	1,6	1
1.3 Did Not Respond	6837	51,7	134	1053	14,9	101	7890	38,8	235
1.4 Incorrect Address	900	6,8	13	727	10,3	36	1627	8,0	49
1.5 Temporarily Absent	113	0,9	8	114	1,6	2	227	1,1	10
1.6 Other	47	0,4	4	70	1,0	11	117	0,6	15
2. Subsequent Invitation/Contact	5794	100,0	228	1043	100,0	168	6837	100,0	396
2.1 Accepted	2249	38,X	457	585	56,1	36	2834	41,5	493
2.2 Refused	216	3,7	48	33	3,2	19	249	3,6	67
2.3 Did not respond	2174	37,5	-484	184	17,6	50	2358	34,5	-434
2.4 Incorrect address	888	15,3	143	182	17,4	41	1070	15,7	184
2.5 Temporarily Absent	193	3,3	31	38	3,6	8	231	3,4	39
2.6 Other	74	1,3	33	21	2,0	14	95	1,4	47

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19,000 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the April 2000

Temporarily Absent - subject is in the military, prison, school, hospital, or on vacation and is temporarily away from his/her permanent address

Subsequent Invitation - an invitation was previously sent to a subject and they refused, didn't respond, or the address was incorrect;
a second or subsequent invitation was sent, possibly with additional information or corrected address (this should be the total number of subjects to whom at least one additional invitation has been sent)

Table 3. Results of Previous Contact with Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only)

	Selection I (Records Selected = 20,071)			Selection II (Records Selected = 14,021)			Total (# of Records = 34,092)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	8432	100.0	227	4819	100.0	329	13251	100.0	556
1. Accepted Invitation	3038	36,0	436	2396	49,7	181	5434	41,0	617
2. Refused Invitation	37	0,4	3	2	0,0	0	39	0,3	3
3. Did Not Respond	2688	31,9	-194	385	8,0	73	3073	23,2	-121
4. Other	2669	31,7	-18	2036	42,2	75	4705	35,5	57

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19,000 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the April 2000

Table 4. Place of Screening for Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only)

	Selection I (Records Selected =20,071)			Selection II (Records Selected = 14,021)			Total (# of Records = 34,092)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	8432	100.0	227	4819	100.0	329	13251	100.0	556
1. Examined at Fixed Center in Kiev	2363	28,0	205	1438	29,8	224	3801	28,7	429
2. Examined by Mobile Team	6069	72,0	22	3381	70,2	105	9450	71,3	127

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Selection I - the first 19,000 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the April 2000

Table 5. Status of Screening Activities for Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only)

	Selection I (Records Selected =20,071)			Selection II (Records Selected = 14,021)			Total (# of Records = 34,092)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination	8432	100,0	227	4819	100,0	329	13251	100,0	556
1. Subject had Complete Screening Examination	8051	95,5	222	4633	96	318	12684	95,7	540
2. Subject Missed Only One Station	343	4,1	5	177	3,7	11	520	3,9	16
2.1 Subject Missed Blood Draw Only	30	0,4	0	6	0,1	0	36	0,3	0
2.2 Subject Missed Urine Collection Only	208	2,5	4	164	3,4	11	372	2,8	15
2.3 Subject Missed Dosimetry Interview Only	100	1,2	1	6	0,1	0	106	0,8	1
2.4 Subject Missed Only One Other Station	5	0,1	0	1	0,0	0	6	0,0	0
3 Subject Missed More than One Station	38	0,5	0	9	0,2	0	47	0,4	0
4. Subject participated in Exit Interview			0			0			

Table 6. Preliminary Results of Screening Examination for Subjects Who Were Screened in Screening Cycle 1 (Baseline Examination Only - from the preliminary endocrine summary completed on the day of the examination)

	Selection I (Records Selected =20,071)			Selection II (Records Selected = 14,021)			Total (# of Records = 34,092)		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Who Came to Screening Examination		100.0			100.0		13251	100.0	556
1. No Thyroid Abnormalities (Follow in 2 Years)							11185	84,41	460
2. Diffuse Goiter							1695	12,79	71
3. Nodular Goiter							287	2,17	18
3.1 At least 1 nodule > 10 mm							103	0,78	13
3.2 At least 1 nodule > 5 mm but none > 10 mm							184	1,39	5
4. Lymphadenopathy							22	0,17	-
5. Thyroiditis (Yes or Suspicion)							41	0,31	1
6. Thyroid Function Disturbance (Yes or Suspicion)							4	0,03	4
7. Parathyroid Disturbance (Yes or Suspicion)							-	-	-
8. Other Thyroid or Neck Pathology (Yes or Suspicion)							1	0,01	-
9. History of Thyroid Surgery Prior to Screening							7	0,05	2
9.1 Thyroid Cancer							5	0,04	1
9.2 Thyroid Adenoma							2	0,01	1
10. History of Other Thyroid Diagnosis Prior to Screening							3	0,02	-
11. Insufficient Information to Complete Preliminary Summary							6	0,04	-

Definitions:

Selection I - the first 20,000 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the April 2000

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Total Subjects Screened - total number of subjects who came to the first screening examination

History of thyroid surgery prior to screening - subject had thyroid surgery before coming to the first screening examination

Table 7. Fine Needle Aspiration Results from Screening Cycle 1 (Baseline Examination Only)

	Cumulative Total		Change Since Previous Quarter
	#	%	#
1. Subject referred for FNA	287	100.0	18
1.1 Subject was screened at Kiev Fixed Center	59	20,56	9
1.2 Subject was screened by Mobile Team	228	79,44	9
1.1a. Subject has NOT undergone FNA	82**	28,57	3
1.1a.1 Subject was screened at Kiev Fixed Center			
1.1a.2 Subject was screened by Mobile Team	82*	28,57	3
1.1b. Subject HAS undergone FNA	205	71,43	20
1.1b.1 FNA positive or suspicious for cancer	26	9,06	4
1.1 b.2 FNA not suspicious for cancer	136	47,39	14
f.1b.3 Sample(s) Inadequate for Diagnosis	43**	14,98	2

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

- in 5 patients (3 revealed by mobile teams in the current quarter, 2 in the previous one) no indications for FNA performance have been found during examination at the Clinic of the Institute of Endocrinology;

** - 2 patients from the previous quarter have undergone repeat biopsy (according to cytology conclusion one patient had a nodular goiter, and one noninformative conclusion).

Table 8. Laboratory Tests Processed

	Cumulative Total		Change Since Previous Quarter
	#	%	#
1. Blood Samples Received	13144	100.0	556
1.1 Blood Samples Processed for TSH	12587	95,76	1512
1.1.1 Blood Samples Processed for Free T4			
1.2 Blood Samples Processed for anti TPO	12588	95,77	1512
1.2.1 Blood Samples Processed for anti Tg	2326	17,70	1 5 1 2
1.3 Blood Samples Processed for Tg	11874	90,34	1512
1.4 Blood Samples Processed for Ca⁺⁺	10401	79,13	0
1.4.1 Blood Samples Processed for PTH	171	1,30	0
2. Urine Samples Received	12824	100.0	541
2.1 Urine Samples Processed	4750	137.0	400

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Samples Received - the number of subjects for whom samples have been received by the laboratory

Samples Processed - the number of subjects for whom each specific laboratory analyses has been completed

Table 9. Final Endocrine Summary Results *

	Selection I			Selection II			Total		
	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter	Cumulative Total		Change Since Previous Quarter
	#	%	#	#	%	#	#	%	#
Total Subjects Screened							13251		556
Final Endocrine Summary Report Completed		100.0			100.0		8181	100.0	2146
1. No thyroid abnormality (Follow in 2 years)							6216	75,98	1830
2. Thyroid abnormality (ICD-9 Code)							1965	24,02	316
2.1 Malignant neoplasm of thyroid gland (193)							27	0,33	7
2.2 Benign neoplasm of thyroid gland (226)							9	0,11	1
2.3 Simple and unspecified goiter (240)							1502	18,27	291
2.4 Nontoxic nodular goiter (241)							69	0,84	8
2.4.1 Uninodular (241.0)							59	0,72	7
2.4.2 Multinodular (241.1)							10	0,12	1
2.5 Thyrotoxicosis with or without goiter (242)							2	0,02	-
2.5.1 Toxic diffuse goiter (242.0)							2	0,02	-
2.5.2 Toxic uninodular goiter (242.1)									
2.5.3 Toxic multinodular goiter (242.2)							-	-	-
2.5.4 Thyrotoxicosis without goiter (242.4 - 242.9)									
2.6 Hypothyroidism (244)							271	3,31	4
2.7 Other Thyroid Disorders (237.4, 245, 246)							84	1,03	5
2.7.1 Autoimmune thyroiditis (245.2)							84	1,03	5
3. Hyperparathyroidism (252.0)									-
4. Hypercalcemia (275.42)							28	0,34	18
Subject Has Been Notified of Examination Results									

Definitions:

Selection I - the first 20,000 subjects who were selected from the dose files

Selection II - the remaining subjects in the dose files who were selected at the April 2000

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Total Subjects Screened - total of the number of subjects who came to the first screening examination

Final Endocrine Summary/Pathology Completed - the total number of subjects for whom the final endocrine summary report has been completed, and Hospitalization Form (if applicable) and Pathology Form (if applicable) have been completed

* Results from final endocrine summary after all laboratory testing is complete and pathology reports obtained (for subjects with FNA/surgery) - Do not include thyroid abnormalities or malignancies diagnosed prior to the first screening

Table 10. Data Management

	Cumulative Total		Change Since Previous Quarter
	#	%	#
Total Subjects Screened	13251	100.0	556
Screening Forms Key Entered	11483	86,7	2480
Dosimetry Questionnaires Key Entered	13151	99,2	551
Urine Processing Forms Key Entered	3320	25,1	0
Blood Processing Forms Key Entered	8785	66,3	851
Final Endocrine Summary Forms Key Entered	8630	65,1	1659
FNA Results Forms Key Entered	148	1,1	43
Pathology Forms Key Entered	0	0,0	0

Definitions:

Cumulative Total - the cumulative total up to the ending date on the title page of this report

Current Quarter - total number for this quarter beginning and ending with the dates on the front page of this report

Total Subjects Screened -total of the numbers reported for Fixed Center and Mobile Teams for Selections I and II from Table 3

Screening Forms Key Entered - total number of subjects for whom all forms filled out on the day of screening (from registration through preliminary endocrine summary) have been key-entered